

**GUAIFENESIN DM- guaifenesin and dextromethorphan syrup**  
**Pharmaceutical Associates, Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**GUAIFENESIN DM**

*Non-Narcotic, Alcohol Free*  
*Expectorant/Cough Suppressant*

**DESCRIPTION**

Each 5 mL (1 teaspoonful)  
contains:

Guaifenesin	100 mg
Dextromethorphan Hydrobromide	10 mg

*Inactive Ingredients:* Citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

*Sodium Content:* 4 mg/5 mL

**USES**

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**WARNINGS**

**Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if**

- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- you are hypersensitive to any of the ingredients.

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Professional Note:** Guaifenesin has been shown to produce a color interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

**DIRECTIONS:** Follow dosage below or use as directed by a physician.

- do not take more than 6 doses in any 24-hour period.

age	dose
adults and children 12 years and over	10 mL (2 teaspoonfuls) every 4 hours
children 6 years to under 12 years	5 mL (1 teaspoonful) every 4 hours
children 2 years to under 6 years	2.5 mL (1/2 teaspoonful) every 4 hours
children under 2 years	ask a doctor

**HOW SUPPLIED:** Guaifenesin Syrup and Dextromethorphan is a red, cherry flavored syrup supplied in the following oral dosage forms:

NDC 0121-0638-04: 4 fl oz (118 mL) bottle

NDC 0121-0638-08: 8 fl oz (237 mL) bottle

NDC 0121-0638-16: 16 fl oz (473 mL) bottle

NDC 01210638-05: 5 mL unit dose cup

NDC 0121-0638-00: Case contains 100 unit dose cups of 5 mL (0121-0638-05) packaged in 10 trays of 10 unit dose cups each.

NDC 0121-1276-10: 10 mL unit dose cup

NDC 0121-1276-00: Case contains 100 unit dose cups of 10 mL (0121-1276-10) packaged in 10 trays of 10 unit dose cups each.

**STORAGE:** Keep tightly closed. Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP]. Protect from light.

**MANUFACTURED BY**

**Pharmaceutical Associates, Inc.**

Greenville, SC 29605

www.paipharma.com

**R11/16**

**PRINCIPAL DISPLAY PANEL - 5 mL Unit Dose Cup Label**

**Delivers 5 mL**

**NDC 0121-0638-05**

**GUAIFENESIN SYRUP  
and DEXTROMETHORPHAN**

**100 mg/10 mg per 5 mL**

**Package Not Child-Resistant**

PHARMACEUTICAL ASSOCIATES, INC.

GREENVILLE, SC 29605

**SEE INSERT**



**PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label**

NDC 0121-0638-04  
NSN 6505-01-318-1565

Quality®  
Value

Guaifenesin-DM

100 mg/10 mg per 5 mL

**EXPECTORANT/COUGH SUPPRESSANT**

Compare to the  
active ingredients in  
\*Robitussin®-DM

**CONTROLS COUGHS**

**LOOSENS AND RELIEVES  
CHEST CONGESTION**

4 fl oz (118 mL)

Pharmaceutical  
Associates, Inc.  
Greenville, SC 29605

NDC 0121-0638-04  
NSN 6505-01-318-1565

**Quality®  
Value**

**Guaifenesin-DM**

**100 mg/10 mg per 5 mL**

**EXPECTORANT / COUGH SUPPRESSANT**

Compare to the  
active ingredients in  
\*Robitussin®-DM

**CONTROLS COUGHS**

**LOOSENS AND RELIEVES  
CHEST CONGESTION**

4 fl oz (118 mL)

**pai** Pharmaceutical  
Associates, Inc.  
Greenville, SC 29605

**Drug Facts**

Active Ingredients (in each 5 mL teaspoonful)	Purpose
Guaifenesin 100 mg	Expectorant
Dextromethorphan Hydrobromide 10 mg	Cough suppressant

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**Warnings**

**Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Drug Facts (continued)**

**Directions** ■ do not take more than 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor

**Other Information**

- store at 20°-25°C (68°-77°F) ■ alcohol-free ■ packaged with tamper-evident seal around cap ■ sodium content 4 mg/5 mL

**Inactive Ingredients** citric acid, FD&C Red No. 40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

\*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.

  
N 3 0121-0638-04 6  
LOT: EXP:  
R11/06

**PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label**

NDC 0121-0638-08

Quality®  
Value

Guaifenesin-DM

100 mg/10 mg per 5 mL

**EXPECTORANT/COUGH SUPPRESSANT**

Compare to the  
active ingredients in  
\*Robitussin®-DM

**CONTROLS COUGHS**

**LOOSENS AND RELIEVES  
CHEST CONGESTION**

**8 fl oz (237 mL)**

**Pharmaceutical  
Associates, Inc.**  
Greenville, SC 29605

**Drug Facts**  
**Active ingredients (in each 5 mL teaspoonful)**  
Guaifenesin 100 mg..... Expectorant  
Dextromethorphan Hydrobromide 10 mg..... Cough Suppressant  
**Purpose**  
**Uses**  
■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive  
■ temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold  
**Warnings**  
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.  
**Ask a doctor before use if you have**  
■ cough that occurs with too much phlegm (mucus)  
■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema  
**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.  
**If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. ►  
\*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.

**Drug Facts (continued)**  
**Directions**  
■ do not take more than 6 doses in any 24-hour period  

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor

**Other Information**  
■ store at 20°-25° C (68°-77° F) ■ alcohol-free  
■ packaged with tamper evident seal around cap  
■ sodium content 4 mg/5 mL  
**Inactive ingredients:** citric acid, FD&C Red No.40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

NDC 0121-0638-08  
**Quality®  
Value**  
**Guaifenesin-DM**  
**100 mg/10 mg per 5 mL**  
**EXPECTORANT / COUGH SUPPRESSANT**  
**Compare to the  
active ingredients in  
\*Robitussin®-DM**  
**CONTROLS COUGHS  
LOOSENS AND RELIEVES  
CHEST CONGESTION**  
**8 fl oz (237 mL)**  
**pai Pharmaceutical  
Associates, Inc.**  
Greenville, SC 29605

**Drug Facts (continued)**  
**Directions**  
■ do not take more than 6 doses in any 24-hour period  

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor

**Other Information**  
■ store at 20°-25° C (68°-77° F) ■ alcohol-free  
■ packaged with tamper evident seal around cap  
■ sodium content 4 mg/5 mL  
**Inactive ingredients:** citric acid, FD&C Red No.40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

  
N 3 0121-0638-08 4  
LOT: EXP:

**PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

**NDC 0121-0638-16**

**Quality®  
Value**

**Guaifenesin-DM**

**100 mg/10 mg per 5 mL**

**EXPECTORANT/COUGH SUPPRESSANT**

Compare to the  
active ingredients in  
\*Robitussin®-DM

**CONTROLS COUGHS**

**LOOSENS AND RELIEVES  
CHEST CONGESTION**

16 fl oz (473 mL)

**Pharmaceutical  
Associates, Inc.**  
Greenville, SC 29605

**Drug Facts**  
**Active ingredients** (in each 5 mL teaspoonful) **Purpose**  
Guaifenesin 100 mg.....Expectorant  
Dextromethorphan Hydrobromide 10 mg.....Cough Suppressant  
**Uses**  
■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive  
■ temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold  
**Warnings**  
**Do not use** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.  
**Ask a doctor before use if you have**  
■ cough that occurs with too much phlegm (mucus)  
■ cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema  
**Stop use and ask a doctor if** cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.  
**If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. ►  
\*Robitussin® is a registered trademark of Wyeth Consumer Healthcare.

NDC 0121-0638-16

**Quality<sup>®</sup>  
Value**

**Guaifenesin-DM**

**100 mg/10 mg per 5 mL**

**EXPECTORANT / COUGH SUPPRESSANT**

Compare to the  
active ingredients in  
\*Robitussin<sup>®</sup>-DM

**CONTROLS COUGHS  
LOOSENS AND RELIEVES  
CHEST CONGESTION**

16 fl oz (473 mL)

**pai** **Pharmaceutical  
Associates, Inc.**  
Greenville, SC 29605

**Drug Facts (continued)**  
**Directions**  
■ do not take more than 6 doses in any 24-hour period  

age	dose
adults and children 12 years and over	2 teaspoonfuls every 4 hours
children 6 years to under 12 years	1 teaspoonful every 4 hours
children 2 years to under 6 years	1/2 teaspoonful every 4 hours
under 2 years	ask a doctor

  
**Other Information**  
■ store at 20°-25° C (68°-77° F) ■ alcohol-free  
■ packaged with tamper evident seal around cap  
■ sodium content 4 mg/5mL  
**Inactive ingredients:** citric acid, FD&C Red No.40, flavoring, glycerin, menthol, purified water, sodium benzoate, sodium citrate, sodium saccharin, and sucrose.

R08/04



N  
3

0121-0638-16

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**PRINCIPAL DISPLAY PANEL - 10 mL Unit Dose Cup Label**

**Delivers 10 mL**

**NDC 0121-1276-10**

**GUAIFENESIN SYRUP**

**and DEXTROMETHORPHAN**

**200 mg/20 mg per 10 mL**

**Package Not Child-Resistant**

**PHARMACEUTICAL ASSOCIATES, INC.**

**GREENVILLE, SC 29605**

**SEE INSERT**





## GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0121-0638
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
<b>DEXTROMETHORPHAN</b> (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-0638-00	10 in 1 CASE	07/01/1992	
1		10 in 1 TRAY		
1	NDC:0121-0638-05	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:0121-0638-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	
3	NDC:0121-0638-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	
4	NDC:0121-0638-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1992	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/1992	

## GUAIFENESIN DM

guaifenesin and dextromethorphan syrup

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0121-1276
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL



<b>DEXTROMETHORPHAN</b> (UNII: 7355X3ROTS) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
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## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0121-1276-00	10 in 1 CASE	07/01/1992	
1		10 in 1 TRAY		
1	NDC:0121-1276-10	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/1992	

**Labeler** - Pharmaceutical Associates, Inc. (044940096)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharmaceutical Associates, Inc.		097630693	manufacture(0121-0638, 0121-1276)